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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,497	09/30/2003	Mark S. Ortiz	END5135-0516315	4657

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EXAMINER	
POUS, NATALIE R	

ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

HH

Office Action Summary	Application No.	Applicant(s)	
	10/675,497	ORTIZ ET AL.	
	Examiner	Art Unit	
	Natalie Pous	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-11,13,15-20 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *4,8-10 and 20* is/are allowed.

6)☒ Claim(s) *1,3,5-7,11,13,15-19 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/22/05,4/30/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Regarding the 35 USC 102 rejections

Applicant's arguments with respect to claims 13 and 15 have been considered but are moot in view of the new ground(s) of rejection based on amendments to the claims.

Regarding Claim 1

Applicant's arguments filed 4/5/07 have been fully considered but they are not persuasive. Applicant argues that Suyker fails to teach a nonexpanding central portion. However, the previous office action denotes the central portion as being comprised of sections 59 and 60 of Suyker, which as seen in figures 37 and 38 do not expand. Thus, Suyker does teach this limitation, and therefore, examiner sustains the previous rejection with respect to Suyker. It is further noted that since the anastomosis ring is not positively claimed, a prior art device must be capable of use with the anastomosis ring described. Since the device of Suyker meets all structural limitations as set forth by the claims, it is inherently capable of performing the function of deploying the described anastomosis ring.

Regarding the 35 USC 103 Rejections

Applicant's arguments filed 4/5/07 have been fully considered but they are not persuasive. Since applicant sustains the previous rejection of claim 1 with respect to Suyker, the teaching references need not teach any missing limitations other than those

disclosed by the previous office action, and thus examiner sustains the previous 35 USC 103 rejections.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 13 rejected under 35 U.S.C. 102(e) as being anticipated by Suyker (US 6485496).

Regarding Claim 13, Suyker teaches a surgical instrument, comprising: a cannula; an actuating member (16) distally and laterally presented on the cannula

capable of receiving a generally cylindrical thermally deformable anastomosis ring, the actuating member formed of a plurality of radially spaced proximal leaves (17) and a plurality of radially spaced distal leaves (17) which each distal leaf outwardly expands by a cantilevered, hinged relationship to a nonexpanding central portion central portion of the actuating member (15, 16); a first control (proximal end of cannula connected to portion 16) operative to move a longitudinal end of the actuating member toward the nonexpanding central portion of the actuating member to expand a respective end portion of the received anastomosis ring; a second control (proximal end of shank 13) to move another longitudinal end (60) of the actuating member toward the nonexpanding central portion of the actuating member to expand the other respective end portion of the received anastomosis ring forming a hollow rivet shape; wherein the first and second controls are capable of being independently actuable to allow independent actuation of either longitudinal end of the actuating member.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1 rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as an obvious matter of design choice.

Regarding Claim 1, Suyker (see embodiment of figs. 37-40) teaches a surgical instrument capable of implanting a thermally deformable anastomotic ring device within a patient, the anastomotic ring device comprising a slidably woven tube of wire at room temperature and an expanded dual headed rivet shape at body temperature, the anastomotic ring device having outer loops or ends which thermally deform and evert when inserted into walls of two adjacent lumens at a luminal interface of an anastomotic site, the ends of the tube everting to form petals in a manner which holds the luminal interface of the anastomotic site into apposition, the surgical instrument comprising: an actuating member (14) formed of a plurality of expandable proximal leaves (61) and a plurality of expandable distal leaves (61, see fig. 38) which each leaf outwardly actuate by a cantilevered hinged relationship to a nonexpanding central portion (59, 60) of the actuating member, and the actuating member moveable between a cylindrical, unactuated position (Fig. 7) and an expanded actuated position having a hollow rivet forming shape (Fig. 11) in response to a compressive actuating force; the actuating member configured to control the expansion of each end of the thermally deformable anastomotic ring device during at least a significant portion of the implantation process; a plurality of distal engaging surfaces (ends of petals 61 not connected to cannula) each

formed on a respective distal leaf spaced away from the central portion and positioned to engage a selected outer loop of a distal portion of the unactuated, cylindrical anastomotic ring for pulling the engaged outer loop proximally and outwardly during actuation; a plurality of proximal engaging surfaces (ends of petals 61 not connected to cannula) each formed on a respective proximal leaf spaced away from the central portion and positioned to engage a selected outer loop of a proximal portion of the unactuated, cylindrical anastomotic ring for pulling the engaged outer loop distally and outwardly during actuation; a handle including an actuation mechanism for producing the compressive actuating force (Column 5, proximate lines 15-19, it is noted that although a handle is not explicitly recited for the embodiment of figs. 37-40, it is inherent that a handle connected to the shank and the sleeve is present to actuate the device, otherwise it would be obvious to one of ordinary skill in the art at the time the invention was made to provide a handle for actuating the device since it is well known in the art to provide a handle on the non-working end of a device for actuation); an elongate cannula (58) configured to position the distal leaves on a distal side of an anastomotic opening and to position the proximal leaves on a proximal side of the anastomotic opening, and configured to transfer the compressive actuating force from the handle to the actuating member wherein the handle is further operably configured to produce the compressive actuating force by producing a proximally directed longitudinal motion and a distally directed longitudinal motion (fig. 37 to fig. 38), the device operably configured to separately transfer the proximally and distally directed longitudinal motions respectively to distal and proximal portions of the actuating member to pivot corresponding distal

and proximal leaves toward each other to actuate the anastomotic ring device from a cylinder shape to a hollow rivet shape (Column 8, proximal lines 57-64).

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Suyker in view of Kim (US 5797920). Suyker teaches all limitations of claim 1, and further teaches wherein the cannula comprises a first tube (58) connected to the proximal portion of the actuating member (59), and a second member (13) slidingly received in the tube and connected to the distal portion of the actuating member (60)

Suyker fails to teach wherein the second member is a tube. Kim teaches an anastomosis device wherein the inner member connected to the distal actuating member (124) is a tube in order to insert tools for controllably expanding or contracting the size of the distal end of the device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Suyker with a tube configuration as taught by Kim in order to insert tools for controllably expanding or contracting the size of the distal end of the device.

Claims 5, 6 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suyker in view of Kim (US 5797920).

Suyker teaches all limitations of preceding dependent claims 1 and 13, but fails to teach wherein the device comprises an enterotomy creation tip distally coupled to the actuating member. Kim teaches wherein the distal end of the device comprises an enterotomy creation piercing tip (130) in order to create an insertion opening for the anastomosis ring and deploy the ring with the same device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the distal

end of Suyker with a enterotomy creation piercing tip as taught by Kim in order to create an insertion opening for the anastomosis ring and deploy the ring with the same device.

Claims 11, 17, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Suyker and Kim and further in view of Yeatman (US 6451029) and further as a matter of design choice.

The combination of Suyker and Kim teaches all aspects of preceding dependent claims 1, 5, 6 and 13 as previously described, but fails to disclose wherein the instrument comprises a pneumatic conduit communicating between the distal tip and the handle for inflating a body lumen, and the tip comprising a veress needle. Yeatman teaches an intestinal stapling device wherein a pneumatic conduit (26) is in communication with the distal tip and handle (30) in order to provide a means of leak testing and performing anastomosis with a common instrument. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Suyker and Kim with a pneumatic conduit communicating between the distal tip and the handle for inflating a body lumen as taught by Yeatman in order to provide a means of leak testing and performing anastomosis with a common instrument.

Regarding the limitation wherein the piercing tip comprises a veress needle, it is noted that a veress needle is one that serves to insufflate a body cavity for a laparoscopic procedure. It is further noted that the combination of Suyker, Kim and Yeatman as described above fulfills that description, and therefore fulfills the structure and function of a veress needle.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Suyker and Kim as applied to claim 6 above, and further in view of Kulkashi et al. (US 5098388). The combination of Suyker and Kim teaches all limitations of preceding dependent claims 1 and 6 as previously described, but fails to teach wherein the piercing tip comprises a veress needle having a syringe knife tip within which a ball translates and springedly withdraws into the Veress needle to expose the piercing surfaces. Kulkashi teaches a veress needle having a syringe knife tip in which a ball translates and springedly withdraws into the Veress needle in order to provide a piercing tip that minimizes the risk of contaminants being carried by gas into the abdominal cavity. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Suyker and Kim with a syringe knife tip in which a ball translates and springedly withdraws into the Veress needle as tough by Kulkashi in order to provide a piercing tip that minimizes the risk of contaminants being carried by gas into the abdominal cavity.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Suyker in view of Park et al. (US 2003/0032967). Suyker teaches all limitations of preceding dependent claim 1 as previously described, but fails to teach wherein the anastomosis ring comprises a woven tube of wire having outer loops or ends which thermally deform and evert when inserted into walls of two adjacent lumens at a luminal interface of an anastomotic site, the ends of the tube everting to form petals in a manner which holds the luminal interface of the anastomotic site into apposition. Park teaches an anastomosis ring (10) comprising a woven tube of wire (18) having outer loops or ends

(20') which thermally deform and evert when inserted into walls of two adjacent lumens at a luminal interface of an anastomotic site (fig. 1), the ends of the tube everting to form petals in a manner which holds the luminal interface of the anastomotic site into apposition (fig. 4) in order to reduce the need for mechanical compression of the anastomosis ring. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Suyker with the anastomosis ring of Park in order to reduce the need for mechanical compression of the anastomosis ring.

Allowable Subject Matter

Claims 4, 8-10 and 20 allowed. The following is a statement of reasons for the indication of allowable subject matter: the prior art alone or in combination fails to teach an anastomotic deployment device comprising all limitations of claim 1 and further wherein a third tube is interposed between the first and second tubes and distally engaged to a central portion of the actuating member, or an electrical illumination source directing illumination proximally toward the actuating member.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tan-Uyen (Jackie) Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
6/18/07

Tanyenho

(JACKIE) TAN-UYEN HO
PRIMARY EXAMINER
6/22/07